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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,180	02/26/2004	Catherine C. Turkel	17679 (BOT)	9912

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EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 05/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/789,180	TURKEL ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/14/04, 7/12/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This action is responsive to Applicant's response filed March 3, 2006.

Withdrawal of Claims

2. Applicant traverses the withdrawal of claims 21-28. Applicant urges that that claims 21-28 should be examined along with claims 1-20. Applicant urges that the invention of claims 21-28 do not differ from the inventions of claims 1-20. Applicant's arguments filed March 3, 2006 have been fully considered but they are not persuasive. For the reasons stated below:

As stated in the previous Office action mailed October 3, 2005, newly submitted claims 21-28 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claims 21-28 are drawn to a method for preventing an acute pain medication overuse disorder comprising a step of local administration of a botulinum toxin concurrently with an acute pain medication to a patient with a headache thereby preventing the acute pain medication overuse disorder. The claims under examination are drawn to a method of treating an acute pain medication overuse disorder comprising a step of local administration of botulinum toxin. Claims 21-28 require that the acute pain medication overuse disorder is prevented or cured. Examined claims 1-20 only require that the disorder is treated. Since, Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution

on the merits. Accordingly, claims 21-28 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

Rejection Withdrawn

4. In view of Applicant's amendment and remarks the rejection of claims 1-20 under 35 U.S.C. 103(a), pages 3-5, paragraph 3 is withdrawn.

Rejection Maintained

5. The rejection double patenting rejection is maintained for claims 1-20 for the reasons set forth on pages 5-6, paragraph 4 of the previous Office action. The rejection was on the grounds that the claims are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of copending Application No. 11/039, 506 filed January 18, 2005. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets claims (claims 1-20 of this application and claims 1-17 of copending Application No. 11/039, 506) are drawn to a method of treating medication overuse patients by administering botulinum toxin to the patients. It should be noted that "triptan medication overuse patients" would be a species of the genus "medication overuse patients". Therefore, the scope of the claims 1-20 of this application would encompass the scope of claims 1-17 of copending Application No. 11/039, 506.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant urges that the double patenting will be addressed upon indication of allowable subject matter.

Applicant's arguments filed March 3, 2006 have been fully considered but they are not persuasive. Applicant has not amended the claims or provided a terminal disclaimer in this application. Therefore, the double patenting rejection will be maintained for the reasons stated above.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Scope of Enablement

6. Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for treating acute pain medication overuse disorder comprising administering up to 260 units of botulinum toxin to a patient in need of such treatment does not reasonably provide enablement for a method for treating acute pain medication overuse disorder comprising administering about 3000 units of botulinum toxin to a patient in need of such treatment.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification provides working examples that disclose a method of treating acute pain medication overuse disorder comprising administering to a patient 105 to 260 total units of BOTOX® (Examples 1-2).

The instant specification has failed to provide enablement for a method of treating an acute pain medication overuse disorder comprising administering about 3000 units to a patient.. It should be noted that the instantly claimed invention encompasses all serotypes of botulinum toxin as well as encompassing botulinum toxin prepared by any manufacture.

The state of the art regarding botulinum toxin administration to subjects (humans) is cited below.

Gil et al *(U.S. Patent No. 6,787,517 published September 7, 2004)* teach that botulinum toxin is the most lethal natural biological agent known to man and has a very potent LD_{50} (column 2). Gil et al teach that a specific dose of a toxin that would be lethal to 50% of the population of a certain species of an animal is called the LD_{50} (column 2). Gil et al teach that the estimated LD_{50} of botulinum toxin A (available from Allergan, Inc., BOTOX®) in humans is about 150,000 picograms or about 3000 units (column 2). Carruthers et al *(U.S. Patent No. 6,358, 917 B1 published March 19, 2002)* teach that botulinum toxin (BTX) is administered in units (column 3). Carruthers et al teach that "unit equivalents" is an amount of botulinum toxin which is equivalent to standard units of botulinum toxin A (column 3). Carruthers et al teach that a standard unit of BTX-A is defined as the L_{50} for female Swiss Webster mice weighing 18-20 grams (column

3). Carruthers et al teach that the estimated human LD_{50} (for a 70-kg person is 40 units/kg or about 2500-3000 units (column 3).

It should be noted that the claimed dosage range includes all botulinum toxins prepared by any manufacturer. The instant specification has failed to enable the claimed method of treating acute medication overuse disorder by administering about 3000 units of any botulinum toxin. Based on the teachings of the cited art the skilled artisan would not administer about 3000units of for example, BOTOX® (botulinum toxin serotype A) to a patient, (e.g. human patient) to treat an autoimmune disorder since the cited art has taught that the estimated human LD_{50} for a 70-kg person is 40 units/kg or about 2500-3000 units of BOTOX®. The instant specification has failed to enable one of skill in the art to make and use the invention commensurate in scope with these claims.

In view of all of the above, Applicant has not satisfied the requirements as set forth under 35 U.S.C. 112 first paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-3, 10-17, 19 and 20 are rejected under 35 U.S.C. 102(a) as anticipated by Schim *(Current Medical Research and Opinion, Vol. 20, No,1, January 2001, p. 49-53).* The claims are directed to a method of treating an acute pain medication overuse disorder caused by overuse of acute pain medication, the method comprising the step of local administration of a botulinum toxin to a patient with acute pain medication thereby treating the acute pain medication overuse disorder caused by overuse of acute pain medication.

Schim teaches a method of treating medication overuse disorder by administering to a patient botulinum toxin (page 51). Schim teaches this method because Schim teaches that botulinum toxin was administered to patients with and without analgesic overuse (Study 3, page 51). Schim teaches that botulinum toxin was effective in treating patients with medication overuse disorder (page 51).

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

8. Claims 1-20 are rejected under 35 U.S.C. 102(a) as anticipated by Tepper et al *(Cephalagia, 2003, 23, 581-762).*

Tepper et al teach a method of treating medication overuse disorder by administering to a patient botulinum toxin (page 715). Tepper et al teach that the patients were administered 100 units of botulinum toxin A (page 715). Tepper et al teach that botulinum toxin was effective in treating patients with medication overuse disorder (page 715).

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

9. Claims 1-20 are rejected under 35 U.S.C. 102(b) as anticipated by Mathew et al *(Headache 2002, 42;454, Abstract S107).*

Matthew et al teach a method of treating medication overuse disorder by administering to a patient botulinum toxin (see the Abstract). Mathew et al teach that the patients with and without analgesic overuse were administered 50 to 100 units of botulinum toxin A to multiple scalp and neck sites (see the Abstract). Matthew et al teach that botulinum toxin was effective in treating patients with medication overuse by reducing the number of chronic migraine and thereby reducing the acute medication use (see the Abstract).

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

10. Claims 1-20 are rejected under 35 U.S.C. 102(b) as anticipated by Blumenfeld *(Headache, 2002; 42:420, Abstract F20).*

Blumenfeld teaches a method of treating medication overuse disorder by administering to a patient botulinum toxin (see the Abstract). Blumefeld teaches that the patients were administered 60 –90 units of botulinum toxin A divided in regions of greatest pain and discomfort: frontalis, corrugator, procerus, temporalis, cervical paraspinals and trapezius muscles (see the Abstract). Blumenfeld teaches that botulinum toxin was effective in treating patients with medication overuse disorder as well as reducing the triptan-specific pharmacy cost (see the Abstract).

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re

Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Status of Claims

11. No claims allowed.

12. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
Biotechnology Patent Examiner
May 7, 2006

NITA MINNIFIELD
PRIMARY EXAMINER